UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

BRENDA ALMOND,

Plaintiff,

v. No: 8:20-cv-731-WFJ-AEP

COLOPLAST A/S;
COLOPLAST CORP.; and
COLOPLAST MANUFACTURING US, LLC

Defendants.

_____/

ORDER GRANTING MOTION TO DISMISS

This matter is before the Court on Defendant Coloplast A/S's Motion to Dismiss, Dkt. 44, Plaintiff Brenda Almond's Amended Complaint, Dkt. 23. Almond filed a response, Dkt. 46, and Coloplast A/S replied, Dkt. 53. After conducting a hearing on December 8, 2020, the Court allowed the parties to conduct limited jurisdictional discovery. Dkt. 56. The Court then held a second hearing on March 25, 2021, and Coloplast A/S filed a supplemental brief, Dkt. 86. With the benefit of full briefing, oral arguments, and the limited jurisdictional discovery conducted by the parties, the Court grants Coloplast A/S's Motion to Dismiss for lack of personal jurisdiction.

BACKGROUND

This case concerns the Altis Single Incision Sling System ("Altis"), a surgical mesh device designed for implantation in a woman's groin and vaginal region to treat pelvic organ prolapse and stress urinary incontinence. Dkt. 23 at 3, 4. On September 25, 2014, Plaintiff Almond received a surgical implant of the Altis device to treat her stress urinary incontinence. *Id.* at 8. This procedure was completed at Florida Hospital Carrollwood in Tampa, Florida. *Id.*

Plaintiff claims the Altis device was defective because it eroded and exposed portions of mesh. *Id.* at 9. This led Plaintiff to experience several health issues, including lower abdominal pain, recurrent urinary tract infections, and chronic vaginal discharge and odor. *Id.* Plaintiff underwent another surgery in March 2017 to have the exposed and eroded portions of the Altis device removed from her body. *Id.* She says she will likely need future medical care and treatment to fix these issues, including future corrective surgery. *Id.*

Plaintiff filed the operative Amended Complaint on June 30, 2020. Dkt. 23. Importantly, Plaintiff Almond sued three defendants: (1) Coloplast Corp.; (2) Coloplast Manufacturing US, LLC; and (3) Coloplast A/S. At issue today is whether this Court has personal jurisdiction over Coloplast A/S. Dkt. 23 at 1.

Coloplast A/S is a foreign corporation incorporated and operating in Denmark. Dkt. 23 at 1. It does not have any offices in the United States, and it

maintains its business records exclusively in Denmark. Dkt. 44 at 2. Coloplast A/S is the parent company of Coloplast Corp. and Coloplast Manufacturing LLC ("the subsidiaries")—both of which are Delaware corporations with their principal places of business in Minnesota. Dkt. 23 at 1–2. The subsidiaries have a distinct and independent management structure from Coloplast A/S. Dkt. 44 at 2. Each subsidiary maintains separate profits and losses from other Coloplast entities, and they maintain their own books and records. *Id.* at 3. Each company observes all corporate formalities. *Id.* The parent does not guarantee the subsidiaries' loans or obligations. *Id.* at 8–9. No employee in Coloplast Corp.'s Interventional Urology business unit reports to any employee of Coloplast A/S about product development, distribution, marketing, clinical, regulatory affairs, or sales. *Id.* at 3.

Coloplast A/S owns the intellectual property rights to the Altis device. Dkt. 89-1 at 76. It submitted a 510(k) application[1] to the U.S. Food and Drug Administration (FDA) in 2012, listing itself as the "Applicant" and "Owner/Operator" of the Altis device. Dkt. 52, Ex. 1 at 2, 14. Coloplast A/S licenses the intellectual property rights for the Altis device to Coloplast Corp. Dkt. 44-1 ¶ 28.

[1] "A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device." *See* U.S. Food & Drug Admin., Premarket Notification 510(k), *available at* https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k (last visited May 19, 2021).

Coloplast Corp. designed and developed the Altis device. Dkt. 89-1 at 74. It also manufactures, distributes, and markets this device, including the specific device implanted into Plaintiff Almond. *Id.* at 79–81. Coloplast A/S does not manufacture, distribute, or market the Altis device. *Id.* In fact, Coloplast A/S does not sell, market, or advertise any female pelvic mesh surgical implants in the United States. Dkt. 44-1 ¶ 24. However, because it owns the intellectual property rights to the Altis device, Coloplast A/S's name and logo appear on the Instructions for Use (IFU) that accompany Altis devices, including the IFU for the device implanted into Plaintiff. *Id.* at ¶ 28. The IFU lists Coloplast A/S as the "manufacturer." *Id.*

Defendant Coloplast A/S now moves for dismissal for lack of personal jurisdiction. Dkt. 44. Plaintiff Almond concedes that Florida does not have general jurisdiction over Coloplast A/S.[2] Thus, the remaining inquiry is whether there is specific jurisdiction over Coloplast A/S.

LEGAL STANDARD

Whether a federal court has personal jurisdiction over a defendant is a question of law. *Consol. Dev. Corp. v. Sherritt, Inc*., 216 F.3d 1286, 1291 (11th Cir. 2000) (citing *Sculptchair, Inc. v. Century Arts, Ltd*., 94 F.3d 623, 626 (11th Cir. 1996)). The plaintiff bears the burden of proof to establish personal

[2] Counsel for Plaintiff Almond conceded this point at the December hearing. Dkt. 61 at 22.

jurisdiction over a nonresident defendant. *See Meier ex rel. Meier v. Sun Int'l Hotels, Ltd*., 288 F.3d 1264, 1268–69 (11th Cir. 2002). To the extent the "plaintiff's complaint and supporting evidence conflict with the defendant's affidavits, the court must construe all reasonable inferences in favor of the plaintiff." *Id.* at 1269 (citing *Madara v. Hall*, 916 F.2d 1510, 1514 (11th Cir. 1990)).

A court must conduct a two-step analysis when evaluating whether it has personal jurisdiction over a defendant. *See Madara*, 916 F.2d at 1514. First, the court must determine whether the plaintiff has alleged facts sufficient to establish a basis for jurisdiction under Florida's long-arm statute. *Id*. This analysis requires application of Florida law. *Id*. Second, if the answer is yes, then the court must determine whether the exercise of jurisdiction satisfies the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution. *Id*. "Only if both prongs of the analysis are satisfied may a federal or state court exercise personal jurisdiction over a nonresident defendant." *Id*.

DISCUSSION

I. The Florida Long-Arm Statute

Plaintiff Almond argues personal jurisdiction is present pursuant to Fla. Stat. § 48.193(1)(a)(6)(b). Dkt. 46 at 4. Under that subsection, a nonresident defendant can submit itself to personal jurisdiction in Florida by:

> 6. Causing injury to persons or property within this state arising out of an act or omission by the defendant outside this state, if, at or about the time of the injury . . .
>
> > b. Products, materials, or things processed, serviced, or manufactured by the defendant anywhere were used or consumed within this state in the ordinary course of commerce, trade, or use.

§ 48.193(1)(a)(6)(b). "Arising from" requires a "direct affiliation, nexus, or substantial connection" between the basis for the cause of action and the defendant's activity in the state. *Wells Fargo Equip. Fin., Inc. v. Bacjet, LLC*, 221 So. 3d 671, 675 (Fla. 4th DCA 2017). Courts should strictly construe the long-arm statute in favor of non-resident defendants. *See Blumberg v. Steve Weiss & Co., Inc.*, 922 So. 2d 361, 363 (Fla. 3d DCA 2006).

Here, the parties do not dispute that the location of the alleged injury was in Florida. Thus, the remaining question is whether Coloplast A/S "processed, serviced, or manufactured" Altis devices used in Florida at or around the time Plaintiff Almond was injured. Plaintiff offers the following two points to buttress her argument that the Florida long-arm statute is satisfied: (1) Coloplast A/S submitted a 510(k) Application to the FDA that listed Coloplast A/S as the "applicant" and "Owner/Operator" of the Altis device; and (2) Coloplast A/S was listed as a "manufacturer" on the IFU for the Altis device implanted into Plaintiff. Dkt. 46 at 4. For the reasons explained below, the Court holds that Plaintiff has failed to establish jurisdiction under § 48.193(1)(a)(6)(b).

The "manufactured" inquiry can be readily handled. According to the jurisdictional discovery conducted by the parties, Coloplast A/S has never manufactured Altis devices in the United States.[3] *See* Dkt. 89-1 at 79 ("Q: Has Coloplast A/S ever been involved in any aspect of the manufacturer [sic] of Altis? A: They have not, no."). Rather, it is Coloplast Corp.—the American subsidiary of Coloplast A/S—that has manufactured all Altis devices since they hit the United States market.[4] *See* Hr'g Tr., p. 4 ("At all points in time Coloplast Corp. and its

[3] Originally, there was some confusion on this point. Claus Ottosen, one of Coloplast A/S's in-house attorneys, provided the following statement during his deposition: "Because Coloplast A/S holds the patent for Altis, Coloplast A/S is listed as the manufacturer on the Altis IFU even though *Coloplast A/S no longer manufactures the Altis*." Dkt. 44-1 ¶ 29 (emphasis added). This statement raised the question of whether Coloplast A/S had manufactured the Altis at some point in time, even though it did not manufacture any now. However, the deposition of James Schumer, Coloplast Corp.'s Vice President of Global Operations (America), cleared this confusion by expressly establishing that Coloplast A/S has never manufactured Altis devices at any point in time. *See* Dkt. 89-1 at 78–79 ("Q: Where Mr. Ottosen says, 'Coloplast A/S no longer manufactures the Altis,' is it your understanding that Coloplast A/S ever manufactured the Altis? A: They did not . . . I mean, this is a mistake. Again, from the time . . . that we started working on the Altis product, we brought on a diversified plastic, who is the manufacturer of the product, to help us with the manufacturing process. They have been the . . . ones that have manufactured the product right from the beginning.").

[4] The mere fact that Coloplast Corp. is a subsidiary of Coloplast A/S does not support jurisdiction over Coloplast A/S. "The activities of a subsidiary cannot be imputed to the parent corporation for purposes of subjecting the latter to long-arm jurisdiction" in Florida. *Hoescht Grp. v. Lozano*, 813 So. 2d 180, 181 (Fla. 3d DCA 2002); *see also State v. Am. Tobacco Co.*, 707 So. 2d 851, 854 (Fla. 4th DCA 1998) (holding that the parent-subsidiary relationship "is insufficient to form a basis for the assertion of personal jurisdiction" over the subsidiary's parent company). Personal jurisdiction over a parent company does not exist unless the parent company exercises "control to the extent the subsidiary manifests no separate corporate interests of its own and functions solely to achieve the purposes of the dominant corporation." *See Vantage View, Inc. v. Bali E. Dev. Corp.*, 421 So. 2d 728, 733 (Fla. 4th DCA 1982) (cleaned up). That is not the case here. Coloplast Corp. has a distinct and independent management structure from Coloplast A/S, it maintains profits and losses separate from Coloplast A/S, its leadership has the right to hire and fire its own employees, it maintains its own books and records, and it otherwise observes all corporate formalities. Dkt. 44-1 ¶¶ 12–13.

contract manufacturer in the United States would have been responsible for design, manufacturing, and marketing of the product here in the United States."). This crucial fact distinguishes this case from the cases on which Plaintiff relies—all of which involved foreign defendants that actually manufactured the offending products at issue. *See, e.g.*, *Knepfle v. J-Tech Corp.*, 419 F. Supp. 3d 1281, 1287 (M.D. Fla. 2019) (holding there was personal jurisdiction over South Korean company that *manufactured* motorcycle helmets later sold and used in Florida); *see also Brown v. Bottling Grp., LLC*, 159 F. Supp. 3d 1308, 1311 (M.D. Fla. 2016) (holding there was personal jurisdiction over German company that *manufactured* construction crane).

Plaintiff makes much of the fact that Coloplast A/S is listed as a "manufacturer" on the IFU and as an "applicant" and "Owner/Operator" on the 510(k) application. However, Coloplast A/S has never actually manufactured the Altis sling. Coloplast A/S is only listed as the manufacturer on the IFU because it owns the intellectual property associated with the Altis sling. Dkt. 89-1 at 76. The same is true for the 510(k) application. *Id.* at 21. At all times Coloplast Corp. and Coloplast Corp.'s American contractor have manufactured these devices. *Id.* at 77. The mere labeling of Coloplast A/S as a manufacturer and owner/operator for intellectual property purposes is not enough to trigger the manufacturing prong of § 48.193(1)(a)(6)(b).

Because Coloplast A/S never manufactured Altis devices, Coloplast A/S is subject to jurisdiction under Florida's long-arm statute only if it "processed or serviced" such devices. The Court concludes it did not.

First, Coloplast A/S did not "process" Altis devices as defined by Florida law. The term "processed" in § 48.193(1)(a)(6)(b) contemplates the "conduct of a wholesaler in bringing together large quantities of goods for shipment." *Blumberg*, 922 So. 2d at 364 (quoting *Wetzel v. Fisherman's Wharf of Pompano Beach, Inc*., 771 So. 2d 1195, 1198 (Fla. 4th DCA 2000)). Examples of "processing" include inspecting, packaging, testing, and distributing products. *See Chatham Steel Corp. v. Brown*, 858 F. Supp. 1130, 1145–46 (N.D. Fla. 1994) (citing *Murante v. Pedro Land, Inc*., 761 F. Supp. 786, 789 (S.D. Fla. 1991)).

Here, Coloplast A/S did not act as a wholesaler for Altis devices. It does not inspect, package, test, or sterilize the devices before they hit the Florida market. *See* Dkt. 89-1 at 79 ("Q: Does Coloplast A/S have any involvement in the manufacturing, sterilization or packaging of Altis? A: They do not, not at all."). Nor does Coloplast A/S have any involvement in the distribution of Altis devices. *Id.* at 80 ("Q: Does Coloplast A/S have any involvement whatsoever in the distribution of Altis throughout the United States? A: They do not, no."). These processes were instead all performed by Coloplast Corp. *Id.* at 79–80. Plaintiff does not explain how the 510(k) application or the IFU fit into this definition of

"processing" under Florida law, and the Court has not found any case law supporting that position. As such, long-arm jurisdiction cannot rest on this basis.

Second, Coloplast A/S did not "service" Altis devices as interpreted by Florida law. "The [long-arm] statute's use of the term 'serviced' connotes some hands-on contact with the product before it comes into the possession of the ultimate consumer." *Plantation-Pioneer Indus. Corp. v. Koehler*, 689 So. 2d 1293, 1295 (Fla. 4th DCA 1997); *see also Hatton v. Chrysler Can., Inc.*, 937 F. Supp. 2d 1356, 1364 (M.D. Fla. 2013) (finding defendant "serviced" a vehicle under the long-arm statute by assembling the vehicle). Even possession of the product is not enough by itself to constitute "service" under the long-arm statute; the defendant must make some hands-on modification to the product before it enters the Florida market. *See Chatham Steel Corp.*, 858 F. Supp. at 1145–46 (refusing to find that defendant "serviced" a product by merely taking possession of it, without making any physical alteration to it prior to product entering Florida); *see also Craker v. Rammtlc, LLC*, No. 09-10078-CIV, 2010 WL 11575069, at *5 (S.D. Fla. Nov. 4, 2010) (same).

Here, Plaintiff Almond makes no allegation that Coloplast A/S had any hands-on contact with Altis devices or physically altered such devices before they entered the Florida market. Instead, the discovery shows this was all performed by Coloplast Corp. and Coloplast Corp.'s American contractor. The Court will not

exert personal jurisdiction over Coloplast A/S based on the actions of its subsidiary alone. *See Meier*, 288 F.3d at 1272. Moreover, Plaintiff does not show how the IFU or the 510(k) application constitute "servicing" under Florida law, and the Court has not found any cases supporting this position.

In sum, the Court concludes Coloplast A/S did not engage in "processing or servicing" under § 48.193(1)(a)(6)(b). *See Andrew v. Radiancy, Inc.*, No. 16-cv-1061-Orl-37GJK, 2017 WL 2692840, at *3–4 (M.D. Fla. June 22, 2017) (finding there was no personal jurisdiction pursuant to § 48.193(1)(a)(6)(b) over a parent company that "did not manufacture, distribute, or sell" the offending device); *Pratte v. Wuebbels*, No. 7-cv-775-Orl-19DAB, 2008 WL 423409, at *3 (M.D. Fla. Feb. 13, 2008) (same). Unlike the cases relied on by Plaintiff, this is not a case where the defendant made the product at issue and put it into the stream of commerce. Coloplast A/S has never manufactured, serviced, processed, distributed, packaged, sterilized, marketed, or sold Altis devices in the United States. In fact, Coloplast A/S does not sell, market, or advertise *any* female pelvic surgical implants in the United States. Dkt. 44-1 ¶ 24. Likely recognizing these limitations, Plaintiff bases her long-arm argument on the fact that the IFU and the 510(k) application list Coloplast A/S as the manufacturer and owner/operator of the Altis device. But this connection does not fit into the requirements of § 48.193(1)(a)(6)(b) as defined by Florida law.

As a final note, Coloplast A/S is a foreign business incorporated and operating in Denmark. It has no office in the State of Florida or anywhere else in the United States. Given Coloplast A/S's insufficient connections to the State of Florida, as well as its minimal contact with Altis devices, the Court concludes that the claims against Coloplast A/S must be dismissed without prejudice.[5] The Court need not address the due process inquiry because Plaintiff Almond has failed to satisfy the Florida long-arm statute.

CONCLUSION

The Court **GRANTS** without prejudice Defendant Coloplast A/S's Motion to Dismiss (Dkt. 44) for lack of personal jurisdiction. The clerk is directed to terminate Coloplast A/S from the case. Plaintiff Almond is no longer entitled to pursue these claims against Coloplast A/S in a Florida court and is therefore foreclosed from amending her complaint to add Coloplast A/S back as a party to this action.

DONE AND ORDERED at Tampa, Florida, on May 21, 2021.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

[5] When a court dismisses claims against a nonresident defendant for lack of personal jurisdiction, this dismissal should be without prejudice. *See Posner v. Essex Ins. Co.*, 178 F.3d 1209, 1221–22 (11th Cir. 1999).

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